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Documents At Issue for Motion to Seal[1]

Bard requests that the following documents be sealed. Bard is not requesting that the documents shaded gray be sealed, however:

A. Bard's Separate Statement of Facts in Support of Their Motion for Summary Judgment Regarding Preemption

B. Exhibits to Defendants' Separate Statement of Facts In Support of Their Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Description
A	03/24/2017	Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption
B	03/24/2017	Declaration of John D. Van Vleet In Support of Defendants' Motion for Summary Judgment Regarding Preemption
C	Aug. 2010	FDA, *CDRH Preliminary Internal Evaluations – Volume I: 510(k) Working Group Preliminary Report and Recommendations*
D	07/28/2014	FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*
E	Jan. 2017	FDA Memorandum, *Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products*
F	11/26/1999	FDA's *Guidance for Cardiovascular Intravascular Filter 510(k) Submissions*
G	01/10/1997	FDA Guidance, *FDA Deciding When to Submit a 510(k) for a Change to an Existing Device* (K97-1)

C. Exhibits to Exhibit A Declaration of Robert Carr In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
1.	11/01/1999	BPV-17-01-00069501 through 69604	NMT's Recovery Filter System Special 510(k) (K993809)

[1] Amended to include new Heading A.

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Ex. No.	Date	Bates No.	Description
2.	12/10/1999	BPV-17-01-00069470 through 69471	Letter FDA to NMT re Recovery (K993809)
3.	02/10/2000	BPV-17-01-00058907 through 58930	Conference FDA and NMT re Recovery (K993809)
4.	02/29/2000	BPV-17-01-00058895	Letter NMT to FDA re Recovery (K993809)
5.	2001	BPV-17-01-00051623 through 51624	Bard acquires filter line from NMT
6.	07/10/2002	BPV-17-01-00057953 through 58037	IMPRA Recovery Permanent Special 510(k) (K022236)
7.	08/05/2002	BPV-17-01-00057926 through 57930	Letter FDA to IMPRA re Recovery (K022236)
8.	08/12/2002	BPV-17-01-00059159 through 59193	Conference IMPRA and FDA re Recovery (K022236)
9.	08/30/2002	BPV-17-01-00057755 through 57917	Letter IMPRA to FDA re Recovery (K022236)
10.	10/04/2002	BPV-17-01-00057740 through 57742	Letter FDA to IMPRA re Recovery (K022236)
11.	10/25/2002	BPV-17-01-00057722 through 57728	Letter IMPRA to FDA re Recovery (K022236)
12.	11/27/2002	BPV-17-01-00057709 through 57711	FDA Clearance Letter re Recovery Permanent (K022236) (Substantial Equivalence)
13.	12/17/2002	BPV-17-01-00062069 through 62070	Letter BPV to FDA requesting conference re Recovery Retrievable
14.	04/25/2003	BPV-17-01-00054947 through 55252	Recovery Retrievable Abbreviated 510(k) (K031328)
15.	07/01/2003	BPV-17-01-00054093	Email FDA to BPV re Recovery Retrievable (K031328)
16.	07/02/2003	FDA_PRODUCTION_ 00001288 through 1291	Email chain FDA and BPV re Recovery Retrievable (K031328)
17.	07/08/2003	BPV-17-01-00054002 through 54076	Fax IMPRA to FDA re Recovery Retrievable (K031328)
18.	07/22/2004	FDA_PRODUCTION_ 00001209 through 1215	Internal FDA Memorandum re Recovery Retrievable (K031328)
19.	07/23/2003	BPV-17-01-00054098 through 54101	Email FDA to BPV re Recovery Retrievable (K031328)
20.	07/23/2003	BPV-17-01-00054109 through 54110	Letter BPV to FDA re Recovery Retrievable (K031328)
21.	07/24/2003	BPV-17-01-00054127 through 54139	Letter BPV to FDA re Recovery Retrievable (K031328)
22.	07/25/2003	FDA_PRODUCTION_ 00001201 through	Internal FDA Memo re Recovery Retrievable (K031328)

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Ex. No.	Date	Bates No.	Description
		1208	
23.	07/25/2003	BPV-17-01-00058122 through 58124	FDA Clearance Letter re Recovery Retrievable (K031328) (Substantial Equivalence)
24.	09/17/2004	BPV-17-01-00097745 through 97746	FDA Contact Report re Recovery IFU and DDL
25.	09/28/2004	BPV-17-01-00097730 through 97733	Conference FDA and BPV re Recovery IFU and DDL
26.	10/05/2004	BPV-17-01-00058083 through 58120	Letter BPV to FDA re Recovery IFU and DDL
27.	11/10/2004	FDA_PRODUCTION_ 00001022 through 1027	Internal FDA Email chain re Recovery IFU and DDL
28.	11/24/2004	BPV-17-01-00029512 through 29516	Email FDA to BPV re Recovery IFU and DDL
29.	11/28/2004	BPV-17-01-00102072 through 102075	Internal BPV Email chain re Recovery IFU and DDL
30.	11/30/2004	BPV-17-01-00058079 through 58081	Letter FDA to BPV re Recovery IFU and DDL
31.	12/2004	BPV-17-01-00043383 through 43402	BPV begins distributing DDL
32.	01/10/2005	BPV-17-01-00043382 through 43402	Conference FDA and BPV re DDL and Recovery Retrievable (K031328)
33.	01/21/2005	BPV-17-01-00097135 through 97137	Conference FDA and BPV re DDL and Recovery Retrievable (K031328)
34.	01/22/2005	BPVE-01-00303306 through 303318	Email from BPV to FDA re DCL and Recovery Retrievable (K031328)
35.	01/27/2005	BPV-17-01-00098579 through 98582	Conference BPV and FDA Phoenix Investigator re DCL and Recovery Retrievable (K031328)
36.	02/04/2005	BPV-17-01-00000208 through 209	Conference FDA and BPV re DCL and Recovery Retrievable (K031328)
37.	02/08/2005	BPV-17-01-00058077	Letter FDA to BPV re Recovery Retrievable (K031328)
38.	02/08/2005	BPV-17-01-00000210 through 211	Conference FDA and BPV re Recovery Retrievable (K031328)
39.	02/08/2005	BPV-17-01-00043415 through 43416	Fax BPV to FDA re DDL and Recovery Retrievable (K031328)
40.	02/14/2005	BPV-17-01-00025340 through 25342	Conference FDA and BPV re DDL and Recovery Retrievable (K031328)
41.	02/28/2005	BPV-17-01-00058041 through 58074	Letter BPV to FDA re FDA AI re Recovery Retrievable (K031328)
42.	02/28/2005	BPV-17-01-00045869 through 45871	Conference FDA and BPV re new submission

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Ex. No.	Date	Bates No.	Description
43.	03/02/2005	BPV-17-01-00125335 through 125415	BPV's Modified Recovery Filter Special 510(k) (K050558)
44.	03/24/2005	BPV-17-01-00097998 through 98003	Conference FDA and BPV re DCL and Modified Recovery (K050558)
45.	03/29/2005	FDA_PRODUCTION_ 00000206 through 22045	Internal FDA memo re Modified Recovery (K050558)
46.	03/30/2005	BPV-17-01-00125312 through 125314	Letter FDA to BPV re Modified Recovery (K050558)
47.	04/19/2005	FDA_PRODUCTION_ 00000193 through 201	BPV's Informal Responses to FDA AI Letter re Modified Recovery (K050558)
48.	04/27/2005	BPV-17-01-00125289	Letter BPV to FDA request 30 day extension re FDA AI Letter re Modified Recovery (K050558)
49.	04/28/2005	BPV-17-01-00125288	Letter FDA to BPV granting 30 day extension re FDA AI Letter re Modified Recovery (K050558)
50.	05/02/2005	FDA_PRODUCTION_ 00000185 through 191	Internal FDA memo reviewing animal study re Modified Recovery (K050558)
51.	05/06/2005	BPV-17-01-00125422 through 125424	Conference FDA and BPV re Modified Recovery (K050558)
52.	05/11/2005	BPV-17-01-00100782 through 100784	BPV Dear Colleague Letter
53.	05/27/2005	BPVE-01-00034167 through 34168	Conference FDA and BPV re Modified Recovery (K050558)
54.	06/03/2005	BPV-17-01-00125416 through 125615	Letter BPV to FDA re Modified Recovery conversion Traditional 510(k) (K050558
55.	07/26/2005	FDA_PRODUCTION_ 00000179 through 183	Internal FDA memo re BPV Responses to FDA AI Letter re Modified Recovery (K050558)
56.	07/26/2005	BPVE-01-00034138	Conference FDA and BPV re Modified Recovery (K050558)
57.	07/27/2005	BPVE-01-00157774 through 157777	Email chain BPV and FDA re Modified Recovery (K050558)
58.	07/28/2005	BPV-17-01-00125220 through 125222	Letter FDA to BPV re AI re Modified Recovery (K050558)
59.	07/28/2005	BPVE-01-00155254 through 155255	Conference FDA and BPV re AI re Modified Recovery (K050558)
60.	08/10/2005	BPV-17-01-00125616 through 125633	Letter BPV to FDA Responses to AI re G2 (K050558)
61.	08/19/2005	BPVE-01-00155084 through 155088	Email BPV to FDA re G2 (K050558)
62.	08/22/2005	BPVE-01-00155392 through 155396	Email BPV to FDA re G2 (K050558)

Ex. No.	Date	Bates No.	Description
63.	08/22/2005	FDA_PRODUCTION_ 00000165 through 168	Internal FDA memo reviewing BPV's Responses to FDA AI re G2 (K050558)
64.	08/26/2005	FDA_PRODUCTION_ 00000158 through 164	Fax FDA to BPV re G2 (K050558)
65.	08/29/2005	FDA_PRODUCTION_ 00000150 through 157	Fax BPV to FDA re G2 (K050558)
66.	08/29/2005	BPVE-01-00154718 through 154723	Email BPV to FDA re G2 (K050558)
67.	08/29/2005	BPV-17-01-00125199 through 125201	FDA Clearance Letter re G2 Permanent (K050558) (Substantial Equivalence)
68.	06/03/2005	BPV-17-01-00125226 through 125285	Email BPV to FDA re proposed IDE G2 Everest Study
69.	07/08/2005	BPV-17-01-00122544 through 122829	BPV's original IDE submission re G2 Everest Study (G050134)
70.	08/05/2005	BPV-17-01-00098772 through 98774	Conference FDA and BPV re G2 Everest Study (G050134)
71.	08/08/2005	BPV-17-01-00122505 through 122508	FDA Grants BPV Conditional Approval for G2 Everest Study (G050134)
72.	08/25/2005	BPV-17-01-00122930 through 122932	Conference FDA and BPV re G2 Everest Study (G050134) and Conditional Approval
73.	10/03/2005	BPV-17-01-00122845 through 122932	Letter BPV to FDA re G2 Everest Study (G051034) and Conditional Approval
74.	10/21/2005	BPVE-01-00275704	Conference FDA and BPV re G2 Everest Study (G051034) and future submission
75.	11/02/2005	BPV-17-01-00122502	FDA Grants Full Approval of G2 Everest Study (G051304)
76.	12/02/2005	BPV-17-01-00123040 through 123067	Letter BPV to FDA re G2 Everest Study (G051304) Notice of IDE Change
77.	06/21/2006	BPV-17-01-00123153 through 123175	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
78.	06/21/2006	BPV-17-01-00123183 through 123210	Letter BPV to FDA re G2 Everest Study (G051304)
79.	07/11/2006	BPV-17-01-00123071 through 123152	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
80.	12/06/2006	BPV-17-01-00123217	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
81.	12/08/2006	BPV-17-01-00123233 through 123249	Letter BPV to FDA re G2 Everest Study (G051304) IDE Supplement
82.	02/02/2007	BPV-17-01-00123269 through 123351	Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report
83.	08/23/2007	BPV-17-01-00123427 through 123474	Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report

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Ex. No.	Date	Bates No.	Description
84.	09/21/2007	BPV-17-01-00123402 through 123405	Letter FDA to BPV Questions re G2 Everest Study (G051304)
85.	10/25/2007	BPV-17-01-00123498 through 123562	Letter BPV to FDA re Responses to FDA re G2 Everest Study (G051304)
86.	12/11/2007	BPV-17-01-00122495	Conference FDA and BPV re G2 Everest Study (G051304)
87.	02/12/2008	BPV-17-01-00123573 through 123588	Letter BPV to FDA re G2 Everest Study (G051304) Final IDE Report
88.	03/12/2008	BPV-17-01-00123564 through 123565	Letter FDA to BPV re G2 Everest Study (G051304) Closing IDE
89.	09/19/2005	BPV-17-01-00125658 through 125749	BPV's G2 Filter - Jugular Subclavian Delivery Kit Special 510(k) (K052578)
90.	09/21/2005	BPV-17-01-00125750 through 125772	Letter BPV to FDA re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
91.	10/13/2005	BPV-17-01-00046358 through 46362	Email FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
92.	10/14/2005	BPV-17-01-00125799 through 125801	Conference FDA and BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
93.	10/14/2005	BPV-17-01-00125804 through 125805	Email FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
94.	10/14/2005	BPV-17-01-00048142 through 48144	Letter FDA to BPV re G2 Filter - Jugular Subclavian Delivery Kit (K052578)
95.	10/25/2005	BPV-17-01-00125782 through 125876	Letter BPV to FDA Responses to FDA AI Demand re G2 Filter - Jugular (K052578)
96.	11/14/2005	BPV-17-01-00125891 through 125892	Conference FDA and BPV re Responses re G2 Filter - Jugular (K052578)
97.	11/16/2005	BPV-17-01-00125893 through 125923	Letter BPV to FDA Responses to FDA AI Demand re G2 Filter - Jugular (K052578)
98.	11/25/2005	BPV-17-01-00125637 through 125639	FDA Clearance Letter G2 Filter - Jugular (K052578) (Substantial Equivalence)
99.	09/25/2006	BPV-17-01-00125963 through 126062	BPV's G2 Filter - Femoral Delivery Kit Special 510(k) (K062887)
100.	10/26/2006	BPV-17-01-00126184 through 126187	FDA Clearance Letter G2 Filter - Femoral Delivery Kit (K062887)
101.	12/04/2006	BPV-17-01-00122493	Conference FDA and BPV re future G2 Filter Retrievable Traditional 510(k)
102.	10/31/2007	BPV-17-01-00123629 through 125197	BPV's G2 Filter Retrievable Traditional 510(k) (K073090)
103.	01/15/2008	BPV-17-01-00123590 through 125592	FDA Clearance Letter G2 Filter Retrievable (K073090) (Substantial Equivalence)
104.	03/07/2008	BPV-17-01-00130498 through 130730	BPV's G2 Express Filter Special 510(k) (K080668)

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Ex. No.	Date	Bates No.	Description
105.	04/08/2008	BPV-17-01-00130470 through 130473	Letter FDA to BPV re AI Demand re G2 Express (K080668)
106.	05/05/2008	BPV-17-01-00131255 through 131261	Letter BPV to FDA Request 30 day extension re G2 Express (K080668)
107.	05/06/2008	BPV-17-01-00130468	Letter FDA to BPV Granting extension re G2 Express (K080668)
108.	05/08/2008	BPV-17-01-00130268 through 130441	Letter BPV to FDA Responses to AI Demand re G2 Express (K080668)
109.	06/06/2008	BPV-17-01-00130460 through 130463	Letter BPV to FDA Responses to AI Demand re G2 Express (K080668)
110.	06/25/2008	BPV-17-01-00117271 through 117272	Conference FDA and BPV re AI Demand re G2 Express (K080668)
111.	06/26/2008	BPV-17-01-00130442 through 130448	Letter BPV to FDA Request 30 Day Extension re G2 Express (K080668)
112.	07/01/2008	BPV-17-01-00130459	Letter FDA to BPV Granting Extension re G2 Express (K080668)
113.	07/02/2008	BPV-17-01-00117260 through 117783	Letter BPV to FDA Responses re AI Demand re G2 Express (K080668)
114.	07/30/2008	BPV-17-01-00130450 through 130452	FDA Clearance Letter G2 Express Filter (K080668) (Substantial Equivalence)
115.	08/12/2008	BPV-17-01-00131320 through 131596	BPV's G2X Filter Special 510(k) (K082305)
116.	09/04/2008	BPV-17-01-00131294 through 131295	Email FDA to BPV re FDA AI Demand re G2X (K082305)
117.	09/08/2008	BPV-17-01-00131298 through 131299	Letter FDA to BPV re FDA AI Demand re G2X (K082305)
118.	09/29/2008	BPV-17-01-00130734 through 130838	Letter BPV to FDA re Responses to FDA AI Demand re G2X (K082305)
119.	10/31/2008	BPV-17-01-00131282 through 131284	FDA Clearance Letter G2X Filter (K082305) Substantial Equivalence
120.	08/14/2009	BPV-17-01-00171823 through 171824	Conference FDA and BPV re future Eclipse Filter 510(k)
121.	11/23/2009	BPV-17-01-00116991 through 117153	BPV's Eclipse Filter System Special 510(k) (K093659)
122.	12/15/2009	BPV-17-01-00171797 through 171799	Letter FDA to BPV re FDA AI Demand re Eclipse (K093659)
123.	12/17/2009	BPV-17-01-00145607 through 145616	Letter BPV to FDA re Responses to FDA AI Demand re Eclipse (K093659)
124.	01/14/2010	BPV-17-01-00117156 through 117158	FDA Clearance Letter Eclipse Filter (K093659) (Substantial Equivalence)
125.	05/20/2010	BPV-17-01-00171679 through 171793	BPV's Eclipse Filter Special 510(k) (K101431)

Ex. No.	Date	Bates No.	Description
126.	06/18/2010	BPV-17-01-00171794 through 171796	Letter FDA to BPV re FDA AI Demand re Eclipse (K101431)
127.	06/21/2010	BPV-17-01-00145617 through 145633	Letter BPV to FDA re Responses to FDA AI Demand re Eclipse (K101431)
128.	06/22/2010	BPV-17-01-00171815 through 171817	FDA Clearance Letter for Eclipse Filter (K101431) (Substantial Equivalence)

D. Exhibits to Exhibit B Declaration of John D. Van Vleet In Support of Defendants' Motion for Summary Judgment Regarding Preemption.

Ex. No.	Date	Bates No.	Description
1.	08/14/2009	BPV-17-01-00171823 through 171824	FDA Contact Report (Eclipse and Platinum Pre IDE)
2.	11/17/2009	BPV-17-01-00171823 through 171824	(Filters and future submissions)
3.	12/03/2009	BPVEFILTER-08-00026072 through 26125	Meridian Pre-IDE Meeting Request
4.	01/08/2010	BPV-17-01-00171850 through 171853	(Meridian Pre IDE)
5.	08/31/2010	BPV-17-01-00150192 through 151045	Meridian Jugular Subclavian Delivery Kit Traditional 510(k) (K102511)
6.	10/26/2010	BPVE-01-01977697 through 1977704	Letter from FDA to BPV re Meridian Jugular (K102511)
7.	11/12/2010	BPV-17-01-00171872 through 171873	(Meridian)
8.	11/16/2010	BPVE-01-01404251 through 1404291	Email to FDA enclosing fatigue testing info re Meridian
9.	12/08/2010	BPV-17-01-00171830 through 171832	FDA Contact Report re Meridian
10.	12/27/2010	BPVEFILTER-01-01201729 through 1201779	Letter from BPV to FDA re Meridian Jugular (K102511)
11.	12/27/2010	BPVEFILTER-11-00002394 through 2960	Appendices to Letter to FDA
12.	02/01/2011	BPVEFILTER-01-00016497 through 16501	Letter from FDA to BPV re Meridian Jugular (K102511)
13.	02/10/2011	BPV-17-01-00171836 through 171838	FDA Contact Report (Meridian)
14.	02/17/2011	BPV-17-01-00171841 through 171844	(Meridian)

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Ex. No.	Date	Bates No.	Description
15.	02/22/2011	BPVEFILTER-01-01853704 through 1853705	Email with FDA re chromosomal aberration testing (Question 3 from Feb. 1 letter)
16.	05/17/2011	BPV-17-01-00171857 through 171864	(Meridian)
17.	05/17/2011	BPVEFILTER-01-00136505	PPT to FDA re Meridian
18.	05/20-23/2011	BPVEFILTER-08-00065051 through 65053	Email chain re deficiencies 8 and 9
19. a.	05/23/2011	BPVEFILTER-08-00076994 through 77147	Letter to FDA re Meridian FDA Questions Feb. 1, 2011 Nos 1-7, 10-13
19.b.	05/23/2011	BPVEFILTER-08-00077067	Letter from BPV to FDA (Appendix 6) Produced in Native Format
19.c.	05/23/2011	BPVEFILTER-08-00077146	Letter from BPV to FDA (Appendix 8) Produced in Native Format
19.d.	05/23/2011	BPVEFILTER-08-00077147	Letter from BPV to FDA (Appendix 8) Produced in Native Format
20.	06/16/2011	BPVEFILTER-01-01138842 through 1138951	Email from custodial file of Joni Creal with Appendix 1-6
21.	06/22/2011	BPV-17-01-00171877 through 171879	(Meridian)
22.	06/27/2011	BPVEFILTER-08-00075953 through 76043	Email from custodial file of Joni Creal with Appendix 1 & 2
23.	06/27/2011	BPVEFILTER-08-00074784 through 74827	Email from custodial file of Joni Creal with Appendix 3-5
24.	06/27/2011	BPVEFILTER-08-00085241 through 85294	Email from custodial file of Joni Creal with Appendix 6 & 7
25.	06/27/2011	BPVEFILTER-08-00083555 through 83592	Email from custodial file of Joni Creal with Appendix 8 & 9
26. a.	06/27/2011	BPVEFILTER-08-00081986 through 82031	Email from custodial file of Joni Creal with Appendix 10 & 11
26.b.	02/10/2011	BPVEFILTER-08-00082031	Letter from BPV to FDA (Appendix 11) Produced in Native Format
27.	06/27/2011	BPVEFILTER-08-00080312 through 80407	Email from custodial file of Joni Creal with Appendix 12 & 13
28.	06/27/2011	BPVEFILTER-01-01156092 through 1156185	Email from custodial file of Joni Creal with Appendix 14 Part A
29.	06/27/2011	BPVEFILTER-35-00027113 through	Email from custodial file of Joni Creal with Appendix 14 Part B

Ex. No.	Date	Bates No.	Description
		27173	
30.	08/17/2011	BPVEFILTER-08-00077841 through 77854	Email with FDA re Meridian IFU changes
31.	08/24/2011	BPV-17-01-00171818 through 171820	Meridian Clearance (K102511)
32.	08/27/2011	BPV-17-01-00147141 through 147592	Femoral Delivery Kit Special 510(k) (K112497) (Vol. I & II)
33.	09/30/2011	BPV-17-01-00147593 through 147597	Letter from FDA to BPV re Meridian Filter System -- Femoral Special 510(k) (K112497)
34.	09/30/2011	BPV-17-01-00147598 through 147607	Letter from BPV to FDA re Meridian Filter System Response to FDA Questions
35.	9/30/2011	BPVEFILTER-01-01138155	Email to FDA enclosing responses to AI (K112497)
36.	10/24/2011	BPVEFILTER-01-01138155	FDA Clearance Letter Meridian Filter System (K112497) (Substantial Equivalence)
37.	08/14/2009	BPV-17-01-00171823 through 171824	FDA Contact Report (Eclipse and Platinum Pre IDE)
38.	03/19/2010	BPVEFILTER-01-01138499 through 1138571	Email to FDA enclosing Denali Pre-IDE
39.	05/05/2010	BPVEFILTER-01-00703843 through 703877	Email enclosing PPT slides for meeting
40.	05/05/2010	BPV-17-01-00171868 through 171871	(Denali Pre IDE)
41.	05/13/2010	BPVEFILTER-01-01110191 through 1110196	Email and meeting minutes re Denali Pre-IDE
42.	05/20/2010	BPV-17-01-00171865 through 171867	(Denali Pre IDE)
43.	06/07/2010	BPVEFILTER-11-00254025 through 254027	FDA Contact Report (Denali Pre-IDE Meeting)
44.	12/10/2010	BPVEFILTER-01-01165336	Email to FDA confirming Denali regulatory strategy
45.	12/30/2010	BPV-17-01-00217546 through 219372	IDE for Denali
46.	02/01/2011	BPVEFILTER-01-00367553 through 367563	FDA Conditional Approval of IDE with 31 questions
47.	02/10/2011	BPV-17-01-00171833 through 171835	FDA Contact Report (Denali Pre IDE)

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Ex. No.	Date	Bates No.	Description
48.	02/16/2011	BPV-17-01-00230270 through 230281	BPV IDE Supplement #1
49.	02/16/2011	BPV-17-01-00230123 through 230269	BPV IDE Supplement #1 appendices
50.	02/22/2011	BPVEFILTER-01-01166624 through 1166626	Email to FDA re biocompatibility questions 27-31
51.	03/11/2011	BPVEFILTER-01-01205839 through 1205845	Email to FDA with proposed response to Nos. 18 and 24
52.	03/16/2011	BPVEFILTER-01-01141999 through 1142002	Email confirming FDA re biocompatibility
53.	03/17/2011	BPV-17-01-00231740 through 231741	FDA letter with conditional approval of IDE
54.	03/21/2011	BPVEFILTER-01-00703650 through 703657	Email from FDA re Questions 18 and 24
55.	08/09/2011	BPV-17-01-00219373 through 220196	BPV 5th IDE Supplement
56.	09/09/2011	BPV-17-01-00231734 through 231736	FDA letter conditional approval of IDE
57.	10/03/2011	BPV-17-01-00220197 through 220258	BPV 7th IDE Supplement
58.	11/03/2011	BPVEFILTER-01-01153526 through 1153528	Letter from FDA requesting more info
59.	11/11/2011	BPV-17-01-00220259 through 220290	BPV 9th IDE Supplement
60.	01/31/2012	BPV-17-01-00230629 through 230644	IDE Annual Report
61.	11/13/2012	BPV-17-01-00230655 through 230749	BPV 13th IDE Supplement.
62.	12/04/2012	BPVEFILTER-01-01170973 through 1170977	Email and attachment to FDA responding to informal questions
63.	12/14/2012	BPV-17-01-00231742 through 231746	FDA Letter approving IDE change.
64.	01/10/2013	BPV-17-01-00230832 through 230904	BPV Annual IDE Report.
65.	02/07/2013	BPV-17-01-00231737 through 231739	FDA Letter with questions re IDE annual report
66. a.	02/08/2013	BPV-17-01-00213103 through 217321	Denali 510(k) submission (K130366) -- Narrative Submission
66.b.	02/08/2013	BPV-17-01-00213189	Denali 510(k) submission (K130366) -- Appendices Part 1

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Ex. No.	Date	Bates No.	Description
66.c.	02/08/2013	BPV-17-01-00213689	Denali 510(k) submission (K130366) -- Appendices Part 2
66.d.	02/08/2013	BPV-17-01-00214188	Denali 510(k) submission (K130366) -- Appendices Part 3
66.e.	02/08/2013	BPV-17-01-00214588	Denali 510(k) submission (K130366) -- Appendices Part 4
66.f.	02/08/2013	BPV-17-01-00215018	Denali 510(k) submission (K130366) -- Appendices Part 5
66.g.	02/08/2013	BPV-17-01-00215974	Denali 510(k) submission (K130366) -- Appendices Part 6
66.h.	02/08/2013	BPV-17-01-00216074	Denali 510(k) submission (K130366) -- Appendices Part 7
66.i.	02/08/2013	BPV-17-01-00216174	Denali 510(k) submission (K130366) -- Appendices Part 8
66.j.	02/08/2013	BPV-17-01-00216474	Denali 510(k) submission (K130366) -- Appendices Part 9
66.k.	02/08/2013	BPV-17-01-00216874	Denali 510(k) submission (K130366) -- Appendices Part 10 Section 1
66.l.	02/08/2013	BPV-17-01-00217098	Denali 510(k) submission (K130366) -- Appendices Part 10 Section 2
67.	03/01/2013	BPV-17-01-00230755 through 230831	BPV response to FDA questions re annual IDE report
68.	03/14/2013	BPV-17-01-00230014 through 230021	Emails with FDA re Denali 510(k)
69.	04/06/2013	BPV-17-01-00229495 through 229498	Email from FDA requesting additional information
70.	04/15/2013	BPV-17-01-00229652 through 229767	Email to FDA responding to questions
71.	04/15/2013	BPV-17-01-00229894 through 229998	Email to FDA responding to questions
72.	04/24/2013	BPV-17-01-00229624 through 229651	Email to FDA responding to questions
73.	05/06/2013	BPV-17-01-00229784 through 229799	Email to FDA responding to questions
74.	05/06/2013	BPV-17-01-00229537 through 229613	Email to FDA responding to questions
75.	05/08/2013	BPV-17-01-00229823 through 229838	Email to FDA with redlined IFU
76.	05/10/2013	BPV-17-01-00229493 through 229494	FDA email to BPV re revised IFU
77.	05/10/2013	BPV-17-01-00229854 through 229868	Email to FDA with revised 510(k) summary

Ex. No.	Date	Bates No.	Description
78.	05/14/2013	BPV-17-01-00229839 through 229853	Emails with FDA re animal study description in 510(k) summary
79.	05/15/2013	BPV-17-01-00217095 through 217097	Denali 510(k) (K130366) Clearance Letter
80.	01/30/2014	BPV-17-01-00230921 through 230999	BPV IDE Annual Report
81.	11/07/2014	BPV-17-01-00217322 through 217528	Denali Special 510(k) (K143208)
82.	12/09/2014	BPV-17-01-00217529 through 217530	Denali Clearance Letter (K143208)
83.	01/30/2015	BPV-17-01-00231017 through 231170	BPV Annual IDE Report
84.	01/29/2016	BPV-17-01-00231188 through 231623	BPV IDE Final Annual Report
85.	02/16/2016	BPV-17-01-00231748 through 231749	FDA email re final IDE and annual report
86.	02/18/2016	BPV-17-01-00231751 through 231756	BPV email responding to questions of Feb. 16
87.	02/26/2016	BPV-17-01-00231750	FDA letter closing Denali IDE

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